

**Notice of Allowability**

Application No.

09/878,466

Applicant(s)

Martin

Examiner

David A Saunders, PhD

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment of 8/20/03 and interview of 11/5/03.
2. ☒ The allowed claim(s) is/are 10-12.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. _____  | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment         |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9 <input type="checkbox"/> Other   |

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Craig Bell on 11/5/03.

The application has been amended as follows:

Cancelled non-elected claims 7-8 sans prejudice.

Cancelled claims 3, 5 and 9 and replaced these with following claims 10-12, respectively.

- -10. A method for the enhancement of the immune system to attack cancerous tumors and inhibit capillary growth to tumors in a mammal comprising the administration of an effective amount of urushiol in a pharmaceutically acceptable carrier together with the co-administration of one or more secondary immunostimulators selected from the group consisting of cytokines, tumor-associated proteins and antigens, tumor vaccines, lipopolysaccharides, Bacillus Calmette-Gurin, immunoglobulin, alpha-interferon, interleukin-2, levamisole, isoprinosine, and mixtures thereof.
- 11. A method for the enhancement of anti-cancer agents for the treatment of cancerous tumors in a mammal comprising the administration of an effective amount of urushiol together with an anti-cancer agent selected from the group consisting essentially of adriamycin, ultra-sound, photo-reactive compounds, anthracyclines, nitrogen mustards, ethyleneamines, methylmelamines, alkyl-sulfonates, nitrosoureas, triazenes, folic acid analogs, pyrimidine analogs, purine analogs and related inhibitors, vinca alkaloids, epipodophyllotoxins, antibiotics, tumor-associated proteins and antigens, biological response modifiers, alpha-interferon, platinum coordination complexes, anthracenedione, substituted-ureas,

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methyldiazine derivatives, adrenocortical suppressants, adrenocorticosteroids, progestins, estrogens, anti-estrogens, androgens, anti-androgens, solvents that destroy cancer cells causing the release of cancer antigens, and mixtures thereof.

12. A method for the treatment of cancer through the enhancement of the immune system to attack cancerous tumor cells and the inhibition of capillary growth to tumors through the simultaneous use of immunostimulators and anti-cancer agents to kill said cells, said method comprising

(i) the administration of an effective amount of urushiol in a pharmaceutically acceptable carrier together with,

(ii) the co-administration of one or more secondary immunostimulators selected from the group consisting of cytokines, tumor-associated proteins and antigens, tumor vaccines, lipopolysaccharides, Bacillus Calmette-Gurin, immunoglobulin, alpha-interferon, interleukin-2, levamisole, isoprinosine, and mixtures thereof together with,

(iii) the co-administration of an anti-cancer agent selected from the group consisting essentially of adriamycin, surgery, ultra-sound, photo-reactive compounds, anthracyclines, nitrogen mustards, ethyleneamines, methylmelamines, alkyl-sulfonates, nitrosoureas, triazines, folic acid analogs, pyrimidine analogs, purine analogs and related inhibitors, vinca alkaloids, epipodophyllotoxins, antibiotics, biological response modifiers, platinum coordination complexes, anthracenedione, substituted-ureas, methyldiazine derivatives, adrenocortical suppressants, adrenocorticosteroids, progestins, estrogens, anti-estrogens, androgens, anti-androgens, solvents that destroy cancer cells causing the release of cancer antigens, and mixtures thereof. --

New claims 10-12 incorporate the Markush groups of immunostimulators and anti-cancer agents, which were previously recited in claims 4 and 6, into the subject matter recited in claims 3, 5 and 9 as presented in the amendment of 8/20/03. This has been done in accord with

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the practice of rejoining non-elected species, upon finding that claims recited with the elected species were patentable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. The examiner can normally be reached on Mon.-Thu., 8:00 am-5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAS 11/5/03

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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